3/25/99

K990438

510(k) Dermaflex™ Wound Dressing
Dermaphylyx, Inc.
K990438

510(k) Summary

Proprietary Name: Dermaflex™ Foam Wound Dressing

Common Name: Dressing

Classification: Unclassified

Submitter's Details:
Dermaphylyx, Inc.
78-E, Olympia Avenue,
Woburn, MA 01801-2057
Tel: (781) 933-4772
Fax: (781) 933-3933

Description:

Dermaflex™ Foam Wound Dressings are sterile, self-adhesive, and absorptive.

Dermaflex provides moist wound environment characteristics and absorptive qualities of traditional therapies in a structure, which is both adhesive and conformable.

The wound contact surface of Dermaflex is composed of a porous adhesive. A second layer consists of a microporous polyurethane foam. The product provides a barrier to exogenous water and dirt while maintaining breathability

Dermaflex Foam Wound Dressings are intended for use in the management of partial and full- thickness wounds in both a professional and OTC environment. They may be used on the following wounds:

- Venous stasis ulcers
- Diabetic ulcers
- Pressure sores
- Donor sites
- Skin Tears
- Burns, (electrical and chemical)
- Abrasions and lacerations
- Incisions
- Burns and abrasions associated with resurfacing procedures such as dermabrasion, chemical, and laser resurfacing

Over the Counter applications include abrasions, minor burns, minor cuts, minor lacerations, and blisters. It may also be used on Poison Ivy and Sunburn.

Dermaflex Wound Dressings are substantially equivalent to Spyroflex®Wound Dressings (Innovative Technologies US, Inc.), and Flexzan Topical Wound Dressings (Dow Hickam Pharmaceuticals, Inc.). These devices are self-adhesive wound dressings, which provide a degree of absorption and breathability. They are intended for use in the management of a wide variety of wounds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 1999

Andrew M. Reed, Ph.D.
Principal
Dermaphylyx, Inc.
12106, West 75th Lane
Arvada, Colorado 80005

Re: K990438
Trade Name:Dermaflex™ Foam Wound Dressing
Regulatory Class: Unclassifed
Product Code: MGP
Dated: February 8, 1999
Received: February 11, 1999

Dear Dr. Reed:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.

2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.

3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597 or at its internet address http://www.fda.gov/cdrh/dsmamain.html.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Dermaflex™ Wound Dressing
Dermaphylyx, Inc.
K990438

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(k) Number: K990438
Dermaphylyx, Inc.

Device Name: Dermaflex™ Foam Wound Dressing

Indications for Use:

Dermaflex Foam Wound Dressings provide a degree of absorption and breathability. They are intended for use in the management of a variety of partial and full-thickness wounds.

The following indications are for Prescription Use or under the direction of a health care professional:

Venous stasis ulcers	Burns, (electrical and chemical)
Diabetic ulcers	Abrasions and lacerations
Pressure sores	Incisions
Donor sites	Burns and abrasions associated with resurfacing procedures
Skin Tears	such as dermabrasion, chemical, and laser resurfacing

The following indications are for Over-the-Counter Use:

Abrasions
Poison Ivy
Sunburn
Minor burns
Minor cuts
Minor lacerations
Blisters

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990438